

Whitehall-Robins Five Giralda Farms Madison, NJ 07940-0871 Telephone (973) 660-5500 Website address: http://healthfront.com

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November 25, 1998

Centrum[®] Herbals St. John's Wort

Notification of Statements on Dietary Supplement Labels

Elizabeth A. Yetley, Ph.D., R.D., Director Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C Street, SW Washington, D.C. 20204

Dear Dr. Yetley:

Reference is made to Centrum® Herbals, St. John's Wort, marketed by Whitehall-Robins Healthcare ("Whitehall-Robins"), a division of American Home Products Corporation.

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, as codified in 21 U.S.C. §343(r)(6), notification is submitted for statements made on the following dietary supplement product that has been marketed within the past 30 days.

Product Name:

Centrum Herbals

St. John's Wort

Ingredient:

St. John's Wort Extract (flower & leaves) Hypericum perforatum

300 mg Capsule

Company Name/

Whitehall-Robins Healthcare

Address:

Five Giralda Farms

Madison, New Jersey 07940

Statements on the Label:

1.) Front Panel of Label:

"helps maintain healthy emotional balance and a positive outlook"

2.) Back Panel of Label:

"This natural product is derived from the flowers and leaves of the St. John's Wort plant. It has been shown in clinical studies to:

• Help maintain healthy emotional balance and a positive outlook."

In accord with 21 CFR §101.93, the disclaimer statement is bolded and boxed on both panels of the carton where the claims appear.

The undersigned certifies that the information contained in this notice is complete and accurate, and that Whitehall-Robins has substantiation that the statements made are truthful and not misleading.

As required, the original and two copies of this notification are enclosed. If you have any questions regarding this information, please contact the undersigned at (973) 660-5751.

Sincerely,

WHITEHALL-ROBINS HEALTHCARE

Eleanor F. Barbo Senior Director Regulatory Affairs